08/718377

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	U.S. Patent No. 5,840,722
Title:	USE OF CARBOXYLIC ACID DERIVATIVES AS DRUGS
Issue Date:	24 November 1998
Inventors:	Ernst Baumann, Uwe Josef Vogelbacher, Joachim Rheinheimer, Dagmar Klinge, Hartmut Riechers, Burkhard Kröger, Siegfried Bialojan, Claus Bollschweiler, Wolfgang Wernet, Liliane Unger, Manfred Raschack
Patent Owner:	Abbott GmbH & Co. KG
Unit:	OPLA
Attn:	Mary C. Till

Mail Stop **Hatch-Waxman PTE**
Office of Patent Legal Administration
Room MDW 7D55
600 Dulany Street (Madison Building)
Alexandria, VA 22314

APPLICATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. §156

Abbott GmbH & Co. KG ("Applicant"), of Max-Planck-Ring 3, 65205 Wiesbaden, Germany, submits this application for extension of patent term of U.S. Patent No. 5,840,722 ("U.S.'722") under 35 U.S.C. §156. The relevant facts establishing the authority of Applicant to file this application for extension of patent term in accordance with 37 C.F.R. §1.730 are set forth below:

- On 4 June 1995, Ernst Baumann, Uwe Josef Vogelbacher, Joachim Rheinheimer, Dagmar Klinge, Hartmut Riechers, Burkhard Kroger, Siegfried Bialojan, Claus Bollschweiler, Wolfgang Wernet, Liliane Unger, Manfred Raschack (inventors of the subject matter claimed in U.S.'722) assigned to BASF Aktiengesellschaft all right, title and interest in their invention. This assignment was recorded in the United States Patent and Trademark Office on 30 September 1996 at Reel 008257, Frame 0686. A copy of this assignment is attached as Exhibit A-1.

- On 18 February 2003, BASF Aktiengesellschaft assigned to Abbott GmbH & Co. KG all right, title and interest in U.S.'722. This assignment was recorded in the United States Patent and Trademark Office on 21 February 2003 at Reel 013746, Frame 0941. A copy of this assignment is attached as Exhibit A-3.

- The Investigational New Drug application ("INDA") for ambrisentan was originally filed by Myogen, Inc. Effective on 17 November 2006, Myogen, Inc. was acquired by Gilead Sciences, Inc. ("Gilead") and became a wholly owned subsidiary known as Gilead Colorado, Inc. A copy of the New Drug application ("NDA") submission letter indicating this fact is attached as Exhibit B.

- Gilead is the exclusive licensee to U.S.'722.

- Gilead is the sponsor of the drug product, LETAIRIS™ (ambrisentan), for which the FDA granted regulatory approval and which forms the basis of this patent term extension. A copy of the approval letter is attached as Exhibit C.

- Applicant is authorized by Gilead to rely on its activities and the activities of its predecessor, Myogen, Inc., before the Food and Drug Administration ("FDA") for regulatory review activities. Gilead has executed a statement authorizing reliance by Applicant on such activities of Gilead. A copy of this statement is attached as Exhibit D.

The following information is submitted in accordance with 35 U.S.C. §156(d) and 37 C.F.R. §§1.740 to 1.741. The formal requirements of 37 C.F.R. §1.740 are specifically set out below.

1. Identification of Approved Product [37 C.F.R. §1.740(a)(1)]

The approved product is LETAIRIS™ (ambrisentan) 5 and 10 mg tablets for the treatment of pulmonary arterial hypertension (WHO Group 1) in patients with WHO class II or III symptoms to improve exercise capacity and delay clinical worsening. See the approved label for LETAIRIS™ tablets provided as Exhibit E. Ambrisentan is the active ingredient in LETAIRIS™ tablets. Ambrisentan is further identified as follows:

A. Chemical Name

The chemical name for ambrisentan is (+)-(2S)-2-[(4,6-dimethylpyrimidin-2-yl)oxy]-3-methoxy-3,3-diphenylpropanoic acid.

The CAS registry number for ambrisentan is 177036-94-1.

B. Generic Name

The generic name of the active ingredient in LETAIRIS™ tablets is ambrisentan. Ambrisentan is the U.S. Adopted Name (USAN) and International Nonproprietary Name (INN) for this compound.

C. Molecular Formula

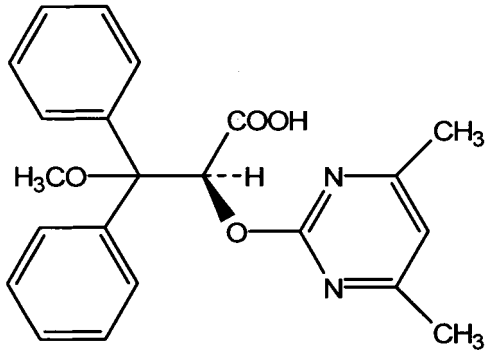
The molecular formula of ambrisentan is $C_{22}H_{22}N_2O_4$.

D. Molecular Weight

The molecular weight of ambrisentan is 378.42.

E. Structural Formula

The structural formula of ambrisentan is:



F. Product Ingredients

Ambrisentan is the active ingredient in LETAIRIS™ tablets, as provided in the approved label text attached as Exhibit E. As provided in Exhibit E, LETAIRIS™ tablets further contain the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. As further provided in Exhibit E, LETAIRIS™ tablets have a film coating containing FD&C Red #40 aluminum lake, lecithin, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

2. Federal Statute under which Regulatory Review Occurred [37 C.F.R. §1.740(a)(2)]

The approved product, LETAIRIS™ tablets, was subject to regulatory review under Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §355(b)(1), as amended.

3. Date of Permission for Commercial Marketing [37 C.F.R. §1.740(a)(3)]

LETAIRIS™ product was approved by the FDA for commercial marketing pursuant to Section 505(b)(1) of the FFDCA on 15 June 2007. A copy of the letter from the FDA to Gilead, dated 15 June 2007, setting forth the approval of the product is attached as Exhibit C.

4. Identification of Active Ingredient and Certifications [37 C.F.R. §1.740(a)(4)]

(a) The active ingredient of LETAIRIS™ is ambrisentan, (+)-(2S)-2-[(4,6-dimethylpyrimidin-2-yl)oxy]-3-methoxy-3,3-diphenylpropanoic acid, having the structure depicted in Section 1 above.

(b) Ambrisentan has not been approved for commercial marketing or use under the FFDCA, the Public Health Service Act, or the Virus-Serum-Toxin Act, prior to the approval granted on 15 June 2007.

(c) The use for which the product is approved is as follows: "LETAIRIS™ is indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) in patients with WHO class II or III symptoms to improve exercise capacity and delay clinical worsening." See the approved label for LETAIRIS™ tablets provided as Exhibit E.

5. Statement of Timely Filing [37 C.F.R. §1.740(a)(5)]

The present application for extension of patent term is being submitted within the sixty-day period permitted for submission under 37 C.F.R. §1.720(f). The FDA approved commercial marketing and use of the approved product, LETAIRIS™ tablets, on 15 June 2007. The sixty-day submission period ends on 13 August 2007. As demonstrated by the signed Certificate of Hand-Delivery, this application for extension of patent term is timely submitted.

6. Identification of Patent for which Extension is Sought [37 C.F.R. §1.740(a)(6)]

U.S. Patent No:	5,840,722
Title:	USE OF CARBOXYLIC ACID DERIVATIVES AS DRUGS
Issue Date:	24 November 1998
Expiration Date:	24 November 2015
Application No.:	08/718,377
Application Filing Date:	23 March 1995 (§371 Date: 30 September 1996)
Inventors:	Ernst Baumann, Uwe Josef Vogelbacher, Joachim Rheinheimer, Dagmar Klinge, Hartmut Riechers, Burkhard Kröger, Siegfried Bialojan, Claus Bollschweiler, Wolfgang Wernet, Liliane Unger, Manfred Raschack
Patent Owner:	Abbott GmbH & Co. KG

7. Patent Copy [37 C.F.R. §1.740(a)(7)]

A copy of U.S.'722, the patent for which extension is being requested, is attached as Exhibit F. This copy contains the entire specification (including claims). There are no drawings in U.S.'722.

8. Disclaimer and Post-Issuance Activity Statement [37 C.F.R. §1.740(a)(8)]

(a) No Disclaimer has been submitted in U.S.'722.

(b) A request for Certificate of Correction was filed on 5 January 1999 and approved as indicated on 26 May 1999. A copy of the approved request for Certificate of Correction and the signed and sealed Certificate dated 27 July 1999 is attached as Exhibit G-1.

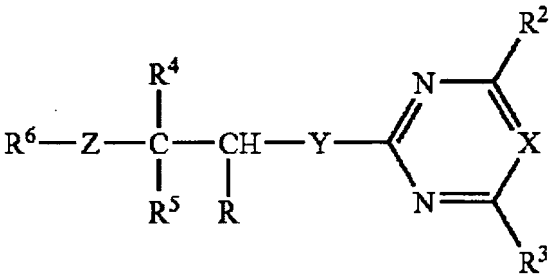
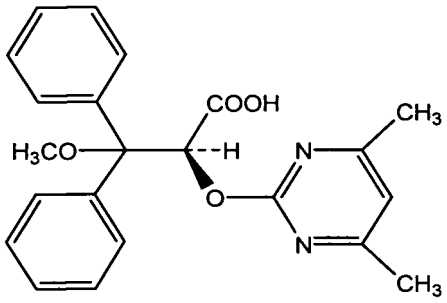
(c) U.S.'722 has not been subject to a Reexamination Proceeding.

(d) The first and second maintenance fees for U.S.'722 were paid on 29 April 2002 and 26 April 2006, respectively. A copy of the maintenance fee statement showing timely payment of all necessary maintenance fees is attached as Exhibit G-2.

9. Statement Showing How the Claims of the Patent Cover the Approved Product [37 C.F.R. §1.740(a)(9)]

The statements in this section are provided solely to comply with the requirements of 37 C.F.R. § 1.740(a)(9). These comments are not an assertion or an admission by the applicant as to the scope of the listed claims, or as to whether or how any of the listed claims would be infringed, literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale or the importation of any product.

U.S.'722 claims a method of using compounds related to the approved product. Claim 1 is set forth below (as corrected in the Certificate of Correction signed and sealed on 27 July 1999) together with a showing of the manner in which each applicable patent claim reads on the approved product. The elements of the Claim 1 which embrace LETAIRIS™ product are shown in bold for convenience.

Claim 1	Ambrisentan
A method of inhibiting endothelin receptors by administering to a patient a compound of the formula I 	
where **R** is formyl, **CO_2H** or a radical which can be hydrolyzed to COOH, and the remaining substituents have the following meanings:	R is carboxyl (COOH, which is the same as CO_2H)
R^2 is halogen, **C_1-C_4-alkyl**, C_1-C_4-haloalkyl, C_1-C_4-alkoxy, C_1-C_4-haloalkoxy or C_1-C_4-alkylthio;	R^2 is methyl (CH_3), which is a C_1 alkyl group
X is nitrogen or **CR^{14} where R^{14} is hydrogen** or, together with R^3, forms a 3- or 4-membered alkylene or alkenylene chain in which, in each case, one methylene group is replaced by oxygen;	X is CH (when R^{14} is hydrogen)
R^3 is halogen, **C_1–C_4-alkyl**, C_1–C_4-haloalkyl, C_1–C_4-alkoxy, C_1–C_4-haloalkoxy, C_1–C_4-alkylthio or R^3 is linked to R^{14} as indicated above to form a 5- or 6-membered ring (as corrected);	R^3 is methyl (CH_3), which is a C_1 alkyl group
R^4 is C_1–C_{10}-alkyl which can carry from one to five halogen atoms and/or one of the following radicals: C_1–C_4-alkoxy, C_1–C_4-alkylthio, cyano, C_1–C_8-alkylcarbonyl, C_1–C_8-alkoxycarbonyl (as corrected), phenyl, phenoxy or phenylcarbonyl, where the phenyl radicals in turn can carry from one to five halogen atoms and/or from one to three of the following radicals: C_1–C_4-alkyl, C_1–C_4-haloalkyl (as corrected), C_1–C_4-alkoxy, C_1–C_4-haloalkoxy (as corrected) and/or C_1–C_4-alkylthio;	R^4 is phenyl, with no substitutions

C_1–C_6-alkyl (as corrected) which can carry from one to five halogen atoms and carries one of the following radicals: a five-membered heteroaromatic ring which contains from one to three nitrogen atoms and/or one sulfur or oxygen atom and which can carry from one to four halogen atoms and/or one or two of the following radicals: C_1–C_4-alkyl, C_1–C_4-haloalkyl, C_1–C_4-alkoxy, C_1–C_4-haloalkoxy, C_1–C_4-alkylthio and/or phenyl;

C_3–C_{12}-cycloalkyl (as corrected) or C_3–C_{12}-cycloalkenyl, each of which can contain one oxygen or sulfur atom and can carry from one to five halogen atoms and/or one of the following radicals: C_1–C_4-alkyl, C_1–C_4-alkoxy, C_1–C_4-alkylthio, cyano, C_1–C_8-alkylcarbonyl (as corrected), C_1–C_8-alkoxycarbonyl, phenyl, phenoxy or phenylcarbonyl (as corrected), where the phenyl radicals in turn can carry from one to five halogen atoms and/or from one to three of the following radicals: C_1–C_4-alkyl, C_1–C_4-haloalkyl, C_1–C_4-alkoxy, C_1–C_4-haloalkoxy and/or C_1–C_4-alkylthio;

C_3–C_6-alkenyl (as corrected) or C_3–C_6-alkynyl (as corrected), each of which can carry from one to five halogen atoms and/or one of the following radicals: C_1–C_4-alkyl, C_1–C_4-alkoxy, C_1–C_4-alkylthio, cyano, C_1–C_8-alkylcarbonyl, C_1–C_8-alkoxycarbonyl, phenyl, phenoxy or phenylcarbonyl, where the phenyl radicals in turn can carry from one to five halogen atoms and/or from one to three of the following radicals: C_1–C_4-alkyl, C_1–C_4-haloalkyl, C_1–C_4-alkoxy, C_1–C_4-haloalkoxy and/or C_1–C_4-alkylthio;

a five- or six membered heteroaromatic ring which contains from one to three nitrogen atoms and/or one sulfur or oxygen atom and which can carry from one to four halogen atoms and/or one or two of the following radicals: C_1–C_4-alkyl, C_1–C_4-haloalkyl (as corrected), C_1–C_4-alkoxy, C_1–C_4-haloalkoxy, C_1–C_4-alkylthio (as corrected), phenyl, phenoxy or phenylcarbonyl, where the phenyl radicals in turn can carry from one to five halogen atoms and/or from one to three of the following radicals: C_1–C_4-alkyl, C_1–C_4-haloalkyl, C_1–C_4-alkoxy, C_1–C_4-haloalkoxy (as corrected) and/or C_1–C_4-alkylthio;

phenyl or naphthyl, each of which can be substituted by one or more of the following radicals: halogen, nitro, cyano, hydroxyl, C_1–C_4-alkyl, C_1–C_4-haloalkyl, C_1–C_4-alkoxy, C_1–C_4-haloalkoxy, phenoxy, C_1–C_4-alkylthio, amino, (as corrected) C_1–C_4-alkylamino or C_1–C_4-dialkylamino; R^4 and R_5 form, together with the adjacent carbon atom, a 3-membered membered ring which can contain one oxygen or sulfur atom and can carry from one to three of the following radicals: C_1–C_4-alkyl, halogen, C_1–C_4-haloalkyl (as corrected), C_1–C_4-alkoxy, C_1–C_4-haloalkoxy and/or C_1–C_4-alkylthio;	
R^5 (as corrected) is hydrogen, C_1–C_4-alkyl, C_3–C_6-alkenyl (as corrected), C_3–C_6-alkynyl (as corrected), C_3–C_8-cycloalkyl (as corrected), C_1–C_4-haloalkyl (as corrected), C_1–C_4-alkoxyalkyl (as corrected), C_1–C_4-alkylthioalkyl, **phenyl** or R_5 is linked to R^4 as indicated above to form a 3- to 8-membered ring;	R^5 is phenyl
R^6 is **C_1-C_8-alkyl** (as corrected), C_3–C_6-alkenyl (as corrected), C_3–C_6-alkynyl (as corrected) or C_3–C_8-cycloalkyl, it being possible for each of these radicals to be substituted one or more times by: halogen, nitro, cyano, C_1–C_4-alkoxy, C_3–C_6-alkenyloxy, C_3–C_6-alkynyloxy (as corrected), C_1–C_4-alkylthio (as corrected), C_1–C_4-haloalkoxy, C_1–C_4-alkylcarbonyl, C_1–C_4-alkoxycarbonyl (as corrected), C_1–C_4-alkylamino, di-C_1–C_4-alkylamino, phenyl, phenoxy or phenyl which is substituted one or more times, e.g. from one to three times, by halogen, nitro, cyano, C_1–C_4-alkyl, C_1–C_4-haloalkyl, C_1–C_4-alkoxy, C_1–C_4-haloalkoxy (as corrected) or C_1–C_4-alkylthio; phenyl or naphthyl, each of which can be substituted by one or more of the following radicals: halogen, nitro, cyano, hydroxyl, amino, C_1-C_4-alkyl, C_1-C_4-haloalkyl, C_1-C_4-alkoxy, C_1-C_4-haloalkoxy, phenoxy, C_1-C_4-alkylthio, C_1-C_4-alkylamino or C_1-C_4-dialkylamino;	R^6 is methyl (CH_3), which is a C_1 alkyl group, with no substitutions

a five- or six-membered heteroaromatic ring which contains from one to three nitrogen atoms and/or one sulfur or oxygen atom and which can carry from one to four halogen atoms and/or one or two of the following radicals: C_1–C_4-alkyl, C_1–C_4-haloalkyl, C_1–C_4-alkoxy, C_1–C_4-haloalkoxy, C_1–C_4-alkylthio (as corrected), phenyl, phenoxy or phenylcarbonyl, where the phenyl radicals in turn can carry from one to five halogen atoms and/or from one to three of the following radicals: C_1–C_4-alkyl, C_1–C_4-haloalkyl, C_1–C_4-alkoxy, C_1–C_4-haloalkoxy and/or C_1–C_4-alkylthio;	
Y is sulfur or **oxygen** or a single bond;	Y is oxygen
Z is sulfur or **oxygen**.	Z is oxygen

Claim 1 reads on a method of using the approved product, LETAIRIS™ tablets, which contains ambrisentan, a compound of formula I.

The use of LETAIRIS™ tablets according to the approved indication necessarily entails the practice of a method according to Claim 1. As recited in the approved label provided as Exhibit E, ambrisentan is an endothelin receptor antagonist:

> "LETAIRIS is an **endothelin receptor antagonist** indicated for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with WHO class II or III symptoms to improve exercise capacity and delay clinical worsening (1)". (emphasis added)

As such, oral administration of LETAIRIS™ tablets, as described in Exhibit E, is a method of inhibiting endothelin receptors.

Therefore, as demonstrated above, Claim 1 of U.S.'722 reads on the approved product, LETAIRIS™ tablets.

10. Statement of Relevant Dates to Determine the Regulatory Review Period [37 C.F.R. §1.740(a)(10)]

The relevant dates and information pursuant to 35 U.S.C. §156(g), in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review period, are as follows:

(a) *Patent Issue Date*

U.S.'722 was issued on **24 November 1998**.

(b) *IND Effective Date [§ 1.740(a)(10)(i)(A)]*

The INDA for the approved product, LETAIRIS™ tablets, was submitted to the FDA on 3 June 2002. A copy of the letter transmitting the INDA to the FDA is attached as Exhibit H. The FDA accorded the INDA a date of receipt of 4 June 2002, and the INDA was assigned number 64,915 ("IND 64,915"). A copy of the letter from the FDA acknowledging receipt of IND 64,915 is attached as Exhibit I. Accordingly, IND 64,915 became effective on **4 July 2002**.

(c) *NDA Submission Date [§ 1.740(a)(10)(i)(B)]*

The NDA for the approved product, LETAIRIS™ tablets, was submitted to the FDA on 13 December 2006. A copy of the letter transmitting the NDA to the FDA is attached as Exhibit B. The FDA accorded the NDA a date of receipt of 18 December 2006, and the NDA was assigned number 22-081 ("NDA 22-081"). A copy of the letter from the FDA acknowledging receipt of NDA 22-081 is attached as Exhibit J. Accordingly, NDA 22-081 became effective on **18 December 2006**.

(d) *NDA Approval Date [§ 1.740(a)(10)(i)(C)]*

NDA 22-081 was approved by the FDA on **15 June 2007**. A copy of the approval letter from the FDA to Gilead is attached as Exhibit C.

11. Brief Description of Activities Undertaken During the Regulatory Review Period [37 C.F.R. §1.740(a)(11)]

A description of significant activities undertaken by the marketing applicant, Gilead through Myogen, Inc. (now Gilead Colorado, Inc. a wholly owned subsidiary of Gilead), during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities are set forth in Exhibit K. Exhibit K is divided into two parts as follows: (K-1) IND 64,915 Chronology and (K-2) NDA 22-081 Chronology.

12. Opinion of Eligibility for Extension [37 C.F.R. §1.740(a)(12)]

In the opinion of Applicant, U.S.'722 is eligible for patent term extension under the provisions of 35 U.S.C. §156. Specifically, Applicant believes that the requirements of 35 U.S.C. §156 for an extension of patent term are satisfied as follows:

(1) Patent with Eligible Subject Matter [35 U.S.C. §156(a)]

The patent has a claim that embraces a method of using the active ingredient of LETAIRIS™ tablets.

(2) Non-expiration of Patent Term [35 U.S.C. §156(a)(1)]

The term of U.S.'722 expires on 24 November 2015, based on a term which is 17 years from the issue date of the patent. Therefore, this application has been submitted before the expiration of the patent term.

(3) No Prior Patent Term extension [35 U.S.C. §156(a)(2)]

The term of U.S.'722 has never been extended.

(4) Owner or Agent [35 U.S.C. §156(a)(3)]

The present application for extension is submitted by the owner of record, Abbott GmbH & Co. KG in accordance with the requirements of 35 U.S.C. §156(d).

(5) Regulatory Review [35 U.S.C. §156(a)(4)]

The approved product was subject to a regulatory review period under Section 505(b)(1) of the FFDCA before its commercial marketing or use (see Exhibits B and H).

(6) First Marketing Approval [35 U.S.C. §156(a)(5)(A)]

The permission for commercial marketing of LETAIRIS™ tablets is the first permitted commercial marketing of ambrisentan.

(7) No Extension of Other Patent [35 U.S.C. §156(c)(4)]

No other patent has been extended for the same regulatory review period for the approved product, LETAIRIS™ tablets.

STATEMENT AS TO LENGTH OF EXTENSION CLAIMED

The extension period of U.S.'722, as calculated below, is **995 days** from the original patent term (24 November 2015) to **15 August 2018.**

Regulatory review period [§1.775(c)]

IND phase [§1.775(c)(1)]

The number of days in the period beginning on the date an exemption under FDCA §505(i) became effective for the approved product (4 July 2002) and ending on the date an NDA was initially submitted under FDCA §505 (18 December 2006)	1629 days

NDA phase [§ 1.775(c)(2)]

The number of days in the period beginning on the date the application was initially submitted for the approved product under FDCA §505 (18 December 2006) and ending on the date the NDA was approved (15 June 2007)	180 days

Total regulatory review period	**1809 days**

Subtractions and limitations [§1.775(d)]

Reduction for regulatory review before patent grant [§1.775(d)(1)(i)]

The number of days in the periods of §1.775(c)(1) (IND phase) and (c)(2) (NDA phase) on or before the date the patent issued (24 November 1998)	0 days

Reduction for lack of due diligence [§1.775(d)(1)(ii)]

The number of days in the periods of §1.775(c)(1) (IND phase) and (c)(2) (NDA phase) during which the applicant did not act with due diligence	0 days

Net subtraction

One-half the number of days remaining in the period of §1.775 (c)(1) (IND phase) after the reductions above	814 days

Net preliminary term extension [§1.775(d)(1)]	**995 days**

Fourteen Year Comparison [§1.775(d)(2)-(4)]

The new expiration date of U.S.'722 with the 995 day extension determined above is 15 August 2018 which is earlier than 15 June 2021, fourteen years from the approval date of NDA 22-081 (15 June 2007).

Five Year Comparison [§1.775(d)(5)]

The 995 day extension calculated above does not exceed five years.

Accordingly, it is respectfully requested that the term of U.S.'722 be extended **995 days** from the original patent term (24 November 2015) to: **15 August 2018.**

13. Duty of Disclosure [37 C.F.R. §1.740(a)(13)]

Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and Secretary of Health and Human Services any information that is material to the determination of entitlement to the extension sought, particularly as that duty is defined in 37 C.F.R. §1.765.

Applicant advises that it is concurrently filing applications under 35 U.S.C. §156 and 37 C.F.R. §1.140, based on the Regulatory Review period for LETAIRIS product, to extend terms of following patents:

-- U.S. Patent No. 5,703,017;

-- U.S. Patent No. 5,840,722;

-- U.S Patent No. 5,932,730; and

-- U.S. Patent No. 7,109,205.

Applicant will, during co-pendency of these four applications, elect one of the four applications to proceed to grant, and will withdraw the remaining three pending applications.

14. Fee Charge [37 C.F.R. §1.740(a)(14)]

The Commissioner of Patents and Trademarks is authorized to charge the prescribed $1,120.00 fee set forth in 37 C.F.R. §1.20(j) for receiving and acting upon this application for extension of patent term, together with any additional fees that may be required during the entire pendency of this application for extension of patent term, to Deposit Account No. 01-0025. A Fee Transmittal (PTO/SB/17) expressly authorizing the charging of fees to Deposit Account No. 01-0025 in this matter is being submitted in duplicate with the pending application for extension of patent term.

15. Correspondence Address [37 C.F.R. §1.740(a)(15)]

Please direct all inquiries and correspondence relating to the application for patent term extension to:

Martin L. Katz
Registration No. 25,011
Wood, Phillips, Katz, Clark & Mortimer
Citigroup Center, Suite 3800
500 West Madison Street
Chicago, IL 60661-2511

Certification under 37 C.F.R. §1.740(b)

The present application of extension of patent term for U.S.'722 is being submitted as one original and two additional copies thereof.

Respectfully submitted,

John D. Conway
Registration No. 39,150
Attorney for Applicant
Abbott Bioresearch Center
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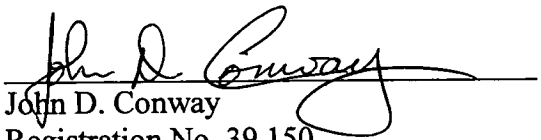
Worcester, MA 01605
Tel.: 508-688-8046
Fax: 508-688-8110

Date: 7 August 2007

CERTIFICATE OF HAND DELIVERY

The undersigned certifies that one original and two duplicate copies of this APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156 (including all Exhibits and supporting papers) are being hand-delivered this 7th day of August 2007, to "Attention: Mary C. Till, Office of Patent Legal Administration, Room MDW 7D55, 600 Dulany Street (Madison Building), Alexandria, VA 22314", United States Patent and Trademark Office.



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	U.S. Patent No. 5,840,722
Title:	USE OF CARBOXYLIC ACID DERIVATIVES AS DRUGS
Issue Date:	24 November 1998
Inventors:	Ernst Baumann, Uwe Josef Vogelbacher, Joachim Rheinheimer, Dagmar Klinge, Hartmut Riechers, Burkhard Kröger, Siegfried Bialojan, Claus Bollschweiler, Wolfgang Wernet, Liliane Unger, Manfred Raschack
Patent Owner:	Abbott GmbH & Co. KG
Unit:	OPLA
Attn:	Mary C. Till

7 August 2007

Mail Stop **Hatch-Waxman PTE**
Office of Patent Legal Administration
Room MDW 7D55
600 Dulany Street (Madison Building)
Alexandria, VA 22314

APPLICATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. §156

In support of the Application for Patent Term Extension of U.S. Patent No. 5,840,722, Applicant submits the following:

1. PTE Application (being submitted as one original and two additional copies thereof)
2. Exhibits A-L
3. Duplicate Fee Transmittal Sheet

Applicant certifies that the two additional copies are identical to the original being submitted.

Respectfully submitted,

John D. Conway
Registration No. 39,150
Attorney for Applicant
Abbott Bioresearch Center
100 Research Drive
Worcester, MA 01605
Tel.: 508-688-8046
Fax: 508-688-8110

Enclosure

HDP/SB/17 (01-07)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2007

Effective 2/8/2006. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 1,120

Complete if Known	
Application Number	Patent No. 5,840,722
Filing Date	March 23, 1995 (Issue Date: November 24, 1998)
First Named Inventor	Ernst Baumann
Examiner Name	
Art Unit	
Attorney Docket No.	

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AUG 07 2007

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 01-0025

Deposit Account Name: Abbott Laboratories

The Director is authorized to: *(check all that apply)*
☒ Charge fee(s) indicated below ☒ Credit any overpayments
☒ Charge any additional fee(s) during the pendency of this application
☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1011	300	2011	150	Utility filing fee	
1012	200	2012	100	Design filing fee	
1013	200	2013	100	Plant filing fee	
1014	300	2014	150	Reissue filing fee	
1005	200	2005	100	Provisional filing fee	

SUBTOTAL (1) ($) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims		-20 ** =	0	X		=	0
Independent Claims		-3 ** =	0	X		=	0
Multiple Dependent						=	0

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	50	2202	25	Claims in excess of 20
1201	200	2201	100	Independent claims in excess of 3
1203	360	2203	180	Multiple dependent claim, if not paid
1204	200	2204	100	** Reissue independent claims over original patent
1205	50	2205	25	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

PATENT EXTENSION
NC PATENTS

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	120	2251	60	Extension for reply within first month	
1252	450	2252	225	Extension for reply within second month	
1253	1020	2253	510	Extension for reply within third month	
1254	1,590	2254	795	Extension for reply within fourth month	
1255	2,160	2255	1080	Extension for reply within fifth month	
1401	500	2401	250	Notice of Appeal	
1402	500	2402	250	Filing a brief in support of an appeal	
1403	1000	2403	500	Request for oral hearing	
1452	500	2452	250	Petition to revive – unavoidable	
1453	1500	2453	750	Petition to revive – unintentional	
1462	400	1462	400	Petition fee under 37 CFR 1.17(f)	
1463	200	1463	200	Petition fee under 37 CFR 1.17(g)	
1464	130	1464	130	Petition fee under 37 CFR 1.17(h)	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	

Other fee (specify) Application of Extension of Patent Term: 1,120

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($)1,120

4. SEARCH/EXAMINATION FEES

1111	500	2111	250	Utility Search Fee
1112	100	2112	50	Design Search Fee
1113	300	2113	150	Plant Search Fee
1114	500	2114	250	Reissue Search Fee
1311	200	2311	100	Utility Examination Fee
1312	130	2312	65	Design Examination Fee
1313	160	2313	80	Plant Examination Fee
1314	600	2314	300	Reissue Examination Fee

SUBTOTAL (4) ($)0

SUBMITTED BY				Complete *(if applicable)*	
Name (Print/Type)	John D. Conway	*Registration No. (Attorney/Agent)*	39,150	*Telephone*	508-688-8046
Signature	John D. Conway			*Date*	August 7, 2007

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	U.S. Patent No. 5,703,722
Title:	USE OF CARBOXYLIC ACID DERIVATIVES AS DRUGS
Issue Date:	24 November 1998
Inventors:	Ernst Baumann, Uwe Josef Vogelbacher, Joachim Rheinheimer, Dagmar Klinge, Hartmut Riechers, Burkhard Kröger, Siegfried Bialojan, Claus Bollschweiler, Wolfgang Wernet, Liliane Unger, Manfred Raschack
Patent Owner:	Abbott GmbH & Co. KG

APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156
EXHIBIT LIST

Exhibit A: Chain of Title/Ownership Recordation
- A-1: Assignment #1
- A-2: Security Agreement
- A-3: Assignment #2
- A-4: Release of Security Interest #1
- A-5: Release of Security Interest #2

Exhibit B: Copy of letter transmitting NDA 22-081 to the FDA

Exhibit C: FDA approval letter of NDA 22-081 to Gilead Sciences, Inc.

Exhibit D: Statement of Reliance

Exhibit E: Approved label for LETAIRIS™ tablets

Exhibit F: Copy of US Patent No. 5,840,722

Exhibit G: Post-Issuance Activity Documents
- G-1: Copy of approved request for Certificate of Correction filed on 5 January 1999, and signed and sealed on 27 July 1999
- G-2: Copy of maintenance fee statement

Exhibit H: Copy of letter transmitting IND 64,915 to the FDA

Exhibit I: Copy of letter from the FDA acknowledging receipt of IND 64,915

Exhibit J: Copy of letter from the FDA acknowledging receipt of NDA 22-081

Exhibit K: Description of significant activities
K-1 IND 64,915 Chronology
K-2 NDA 22-081 Chronology

Exhibit L: Calculation of Length of Patent Term Extension for a Human Drug Product